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|---|-------------|----------------------|---------------------------------|-----------------------------|
| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO.            |
| 10/776,311  | 02/11/2004  | Anthony J. Kinney    | BB1538USNA                      | 4023                        |
| 23906 7590 02/06/2008<br>E I DU PONT DE NEMOURS AND COMPANY<br>LEGAL PATENT RECORDS CENTER<br>BARLEY MILL PLAZA 25/1122B<br>4417 LANCASTER PIKE<br>WILMINGTON, DE 19805 |             |                      | EXAMINER<br>FOX, DAVID T        |                             |
|   |             |                      | ART UNIT<br>1638                | PAPER NUMBER                |
|   |             |                      | NOTIFICATION DATE<br>02/06/2008 | DELIVERY MODE<br>ELECTRONIC |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTO-Legal.PRC@usa.dupont.com

## Office Action Summary

Application No.

10/776,311

Applicant(s)

KINNEY ET AL.

Examiner

David T. Fox

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,11,12,16-18,21-28 and 140 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 and 140 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,11,12,16-18 and 26-28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### ***Claim Objections***

Applicant's amendments of 19 November 2007 have overcome all claim objections except as indicated below.

Claim 12 remains objected to for non-compliance with 37 CFR 1.121(c), for failing to underline the newly added "docosahexaenoic acid (DHA)".

In the amendment of 21 September 2006, claim 12 merely recited the three abbreviations "EPA, DPA, and DHA". In response to the Examiner's rejection of this claim as being indefinite, Applicant amended the claim on 23 March 2007 to introduce the full-length names of each of these fatty acids, followed by their abbreviations in parentheses, and deleted the original recitation of "EPA, DPA, and DHA". However, only the first two fatty acids' full names were underlined in that amendment. The penultimate line of claim 12 of that amendment only underlines "eicosapentaenoic acid (EPA), docosapentaenoic acid (DPA), and". The ultimate line of claim 12 of that amendment does not underline "docosahexaenoic acid (DHA)".

### ***Obviousness-Type Double Patenting***

Claims 1, 11-12, 16-18 and 26-28 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 11/624,777. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the reasons presented in the last Office action on pages 3-4.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 19 November 2007 have been fully considered but they are not persuasive. Applicant urges that claims 11-12, 16-18 and 26-28 of the copending application have been cancelled, and that claim 1 of the copending application will be canceled.

The obviousness-type double patenting rejection will be maintained until claim 1 of the copending application has in fact been cancelled.

***Enablement***

The enablement rejection has been withdrawn-in-part, based upon Applicant's arguments in the amendment of 19 November 2007.

Claims 1, 11-12, 16-18 and 26-28 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for oilseed plants which produce mature seeds comprising at least 1% of at least one of EPA, DPA or DHA, wherein said plants have been transformed with at least two desaturase genes and at least one corresponding elongase gene from the same pathway as at least one of the desaturase genes; does not reasonably provide enablement for claims broadly drawn to any oilseed plant of any genotype which produces mature seeds comprising at least 1.0% of any polyunsaturated fatty acid having at least twenty carbon atoms and five or more carbon-carbon double bonds. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on page 4 of the last Office action.

Applicant's arguments filed 19 November 2007 have been fully considered but they are not persuasive. Applicant urges that a variety of workers have obtained a variety of oilseed plants with the claimed levels of polyunsaturated fatty acids, using a variety of genes which are involved in a variety of metabolic pathways.

The Examiner maintains that all of the workers cited in Robert et al (2006) appear to have transformed the plants with at least two desaturase genes, particularly delta 5- and delta 6- desaturase genes, and at least one elongase gene, particularly delta-5 or delta 6- elongase genes (see, e.g., page 105, Table 1). Moreover, Napier et al (2006) state that Abbadi et al only obtained 0.8% EPA in transgenic flax (see, e.g., page 401, column 1, first full paragraph), and that "species-specific bottlenecks" also occurred (see, e.g., page 401, column 2, top paragraph). In addition, Wu et al (2005) teach that DHA levels could be as low as 0.2% (see, e.g., page 1014, column 1, second full paragraph); while Robert et al (2006) taught that in Arabidopsis, DHA levels were only 0.5% (see, e.g., page 105, Table 1).

Thus, Applicant and others have only demonstrated the accumulation of the claimed level of polyunsaturated fatty acids when particular classes of transgenes were introduced, and wherein only particular fatty acids accumulated to the claimed levels. In contrast, the claims are not limited to the use of any transgene, and most are not limited to the accumulation of any particular fatty acid.

***Written Description***

Claims 1, 11-12, 16-18 and 26-28 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s)

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 4-5 of the last Office action, with respect to the type of transgene introduced, as stated above for the modified enablement rejection.

Applicant's arguments filed 19 November 2007 have been fully considered but they are not persuasive. Applicant urges that the written description rejection is improper, for the same reasons that the enablement rejection is improper.

The Examiner has withdrawn the written description rejection as it pertains to recipient plant species, but maintains it for the introduction of particular transgenes. The claims broadly encompass plants with any type of genetic material that somehow results in the accumulation of particular polyunsaturated fatty acids at particular levels. However, this genus is much broader than the exemplified species of desaturase and elongase transgenes, and Applicant has not provided any conserved sequences within the broadly claimed genus which are associated with the function of producing the desired accumulation of particular fatty acids.

Applicant's comments regarding DPA accumulation in transgenic soybeans are noted. The Examiner notes that the bulk of the references cited by Applicant demonstrate that DPA accumulation is lower than 1% in many non-soybean plant species, even when transformed with the exemplified types of transgenes. Thus, non-soybean plants which produce the claimed levels of fatty acids including DPA,

containing a multitude of non-exemplified and undescribed transgenes or native genes, have not been reduced to practice.

**Conclusion**

The claims remain free of the prior art, as stated on page 6 of the last Office action.

Applicant is reminded to provide basis for any claim amendment which might be submitted in response to this Office action.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (571) 272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

Application/Control Number:  
10/776,311  
Art Unit: 1638

Page 7

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached on 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 01, 2008

DAVID T. FOX  
PRIMARY EXAMINER  
GROUP 180-1638

